FDA Public Health Notification:
Reducing Radiation Risk from
Computed Tomography for
Pediatric and Small Adult Patients
(You are encouraged to copy and distribute this information)

November 2, 2001

To:
Radiologists
Radiation Health Professionals
Risk Managers
Hospital Administrators

While the benefits of computed tomography are well known in diagnosing diseases and trauma and in the guidance of interventional and therapeutic procedures, those benefits are not without risks. This Notification is to-emphasize the importance of keeping radiation doses during CT procedures as low as reasonably achievable, especially for pediatric and small adult patients, who may sometimes receive more radiation than needed to obtain diagnostic images. To prevent this, we want to stress the importance of adjusting CT scanner parameters appropriately for each individual's weight and size, and for the anatomic region being scanned.

Background

The individual risk from the radiation associated with a CT scan is quite small compared to the benefits that accurate diagnosis and treatment can provide. Still, unnecessary radiation exposure during medical procedures should be avoided. This is particularly important when the patient is a child, since children exposed to radiation are at a relatively greater risk than adults.1 The American College of Radiology has noted, "Because they have more rapidly dividing cells than adults and have longer life expectancy, the odds that children will develop cancers from x-ray radiation may be significantly higher than adults."2 It has been estimated by the National Research Council's Committee on the Biological Effects of Ionizing Radiation that children less than 10 years of age are several times more sensitive to radiation than middle-aged adults.3 Unnecessary radiation may be delivered when CT scanner parameters are not appropriately adjusted for patient size.4 When a CT scan is performed on a child or small adult with the same technique factors that are used for a typically-sized adult, the small patient receives a significantly larger effective dose than the full-sized patient.

To compound the problem, the overexposure of children or small

adults during CT procedures can easily go unrecognized. In conventional x-ray procedures, medical personnel can tell if the patient has been overexposed because the resulting film is overexposed, producing a dark image.5 But with CT, there is no obvious evidence that the patient has been overexposed because the quality of the image may not be compromised.

Several recent articles stress that it is important to use the lowest radiation dose necessary to provide an image from which an accurate diagnosis can be made, and that significant dose reductions can be achieved without compromising clinical efficacy.2, 5, 6, 7, 8, 9, 10

Recommendations

Here are the steps we are recommending. They are not new. Indeed, many facilities are already taking measures to protect children and other small patients from unnecessary exposure during CT procedures.11, 12, 13

1. Optimize CT Settings. Based on patient weight or diameter and anatomic region of interest, evaluate whether your CT operating conditions are optimally balanced between image quality and radiation exposure. To reduce dose while maintaining diagnostic image quality:
* Reduce tube current. With all other factors held constant, patient radiation dose is directly proportional to x-ray tube current. For example, a 50 percent reduction in tube current results in a 50 percent decrease in radiation dose.9
* Develop and use a chart or table of tube-current settings based on patient weight or diameter and anatomical region of interest. See reference 9 for an example of tube current settings based on patient weight and anatomical region of interest (i.e., chest, pelvis or abdomen) for a single-detector helical-scanning CT unit. The diameter of the patient may be a better predictor of the tube-current required than body weight because patient diameter better correlates with the x-ray beam attenuation in the patient.10 Your facility's medical physicist and the scanner manufacturer can help in developing this chart or table.
* Increase table increment (axial scanning) or pitch (helical scanning). If the pitch is increased, the amount of radiation needed to cover the anatomical area of interest is decreased.2, 14 One study showed that increasing the pitch from 1:1 to 1.5:1 decreased the radiation dose by 33 percent without loss of diagnostic information.15 Consult your facility's medical physicist, who can advise you on optimal tube-current and pitch settings for diagnostic requirements. You can also contact the manufacturer of the CT scanner for recommendations specific to your model.

Note that some newer CT scanners may automatically suggest or implement an increase in mA if pitch is increased. For these models, increasing the pitch may not result in a lower radiation dose. Contact the CT

scanner's manufacturer for recommendations on your model's automatic current adjustment features.

2. Reduce the number of multiple scans with contrast material.
Often, CT scans are done before, during, and after injection of IV contrast material. When medically appropriate, multiple exposures may be reduced by eliminating pre-contrast images (i.e., unenhanced images). 9

3. Eliminate inappropriate referrals for CT. In some cases, conventional radiography, sonography, or magnetic resonance imaging (MRI) can be just as effective as CT, and with lower radiation exposure. Most conventional x-ray units deliver less ionizing radiation than CT systems, and sonography and MRI systems deliver no x-ray radiation at all. It is important to triage these examinations to eliminate inappropriate referrals or to utilize procedures with less or no ionizing radiation.9

Reporting adverse events to FDA

We encourage you to report computed tomography equipment malfunctions. You can report these directly to the device manufacturer. You can also report to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch one of four ways: online at http://www.accessdata.fda.gov/scripts/medwatch/; by telephone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; or by mail to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857.

Getting more information

If you have questions regarding this letter, please contact Marian Kroen, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, by fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov. Additionally, a voice mail message may be left at 301-594-0650, and your call will be returned as soon as possible.

All of the FDA medical device postmarket safety notifications can be found on the World Wide Web at http://www.fda.gov/cdrh/safety.html. Postmarket safety notifications can also be obtained through e-mail on the day they are released by subscribing to our list server. You may subscribe at http://list.nih.gov/archives/dev-alert.html. You may also subscribe by sending an email to listserv@list.nih.gov. In the body of the text, type "SUBSCRIBE DEV-ALERT firstname lastname".

Sincerely yours,

David W. Feigal, Jr., MD, MPH Director Center for Devices and Radiological Health Food and Drug Administration

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